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November 29, 2012

Via ECF and FEDEX

The Honorable Esther Salas
United States District Judge
M.L. King, Jr. Federal Bldg. & Courthouse, 2D
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Re: *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*
Civil Action No. 2:10-cv-06108 (ES)(CLW)

Dear Judge Salas:

We along with Locke Lord LLP represent defendant Roxane Laboratories, Inc. in the above-captioned action. We submit this reply letter-brief in support of Roxane's motion for leave to amend its invalidity and noninfringement contentions (D.I. 177/178) because the Court's September 14, 2012 *Markman* Opinion contained claim constructions that differed from Roxane's proposed constructions.

Nothing Jazz argues in its opposition-letter brief (D.I. 184/185) changes the fact that there is good cause for Roxane's proposed contention amendments (D.I. 178-1, Ex. A through D.I. 178-5, Ex. E; D.I. 177, Ex. F). The Court's claim construction rulings that differed from Roxane's proposed constructions necessitated each and every proposed amendment. Local Patent Rule 3.7(a) specifically provides for amendment of a contention in this precise situation where "absent undue prejudice to the adverse party" there is "a claim construction by the Court different from that proposed by the party seeking amendment." Here, Jazz has not argued any undue prejudice. And as shown in the table below, for each of the claim terms under which Roxane seeks amendment, the Court adopted a construction that is different from Roxane's proposed construction:

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Claim Term	Roxane's Proposed Construction	Court Construction
"adding the gamma-hydroxybutyrate salt to the aqueous medium"	Externally adding a pre-made gamma-hydroxybutyrate salt into a pre-existing aqueous medium. D.I. 77 at 10.	No construction needed stating that the salt "could form <i>in situ</i> in the aqueous solution" and that "there is no limitation how it gets there." D.I. 151 at 9, 11.
"pH adjusting agent"	An agent, which is an acid or base, directly added primarily to alter the pH. D.I. 77 at 13.	Compositions that achieve a desired pH. D.I. 151 at 19-21.
"organic acid"	An acid containing at least one carbon atom that directly acidifies a solution. D.I. 77 at 14.	A substance containing at least one carbon atom that lowers pH. D.I. 151 at 22.
"selecting . . . multiple controls" and "places controls"	Deciding to select more than one control. D.I. 77 at 31-32.	No construction necessary. D.I. 151 at 30-31.
"controls selected from the group consisting of"	Selected from the group consisting of the listed controls and no others. D.I. 77 at 32.	No construction necessary. D.I. 151 at 31.
"the controls comprising"	Including all of the recited controls but open to additional controls. D.I. 77 at 33-34.	No construction necessary. D.I. 151 at 31-33.

Jazz's arguments in response to Roxane's motion are also inadequate to strip Roxane of its right to amend under the Local Patent Rules where the Court has adopted a construction for a claim element that is different from that which Roxane proposed. First, the cases Jazz cites in support of its argument that Roxane's amendments should be denied are distinguishable.

Second, Jazz's argument that Roxane's contention amendments must be limited to only those claim elements that explicitly contain the disputed claim terms is incorrect. Here, the Court's construction of certain claim terms also affected Roxane's contentions for certain claim elements wherein the disputed claim terms do not literally appear, but are implicit in the claim scope. Thus, amendment is appropriate.

Third, Jazz argues that Roxane should be precluded from amending where it could have earlier sought amendments in response to Jazz's infringement contentions. Jazz's argument misses the point. Roxane is not seeking amendment under Local Rule 3.7(d). Roxane's original contentions were complete based on the constructions Roxane believed were applicable. Roxane was under no obligation to amend its contentions based on Jazz's proposed constructions that Roxane did not believe were applicable. The Court rejected Roxane's (and Jazz's) proposed constructions and under that circumstance, Local Patent Rule 3.7(a) plainly authorizes amendment. Indeed, it would be manifestly unfair to tether a party to contentions offered before the Court issued its claim construction as the party obviously could not anticipate how the Court would ultimately construe the claim terms.

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Fourth, Jazz argues that instances where the Court decided that no construction is necessary do not fall within Local Patent Rule 3.7(a). However, in deciding that no construction was necessary, the Court necessarily rejected Roxane's proposed construction and adopted a construction different from what Roxane proposed.

Last, the amendments are more than just a rewording of Roxane's initial contentions—they are substantive amendments. But even if they are deemed to be a rewording, that too is permitted. There is no rule or law that dictates the type of amendment that could be proposed following a claim construction by the Court that is different from Roxane's proposed constructions.

1. The *Convolve*, *Finisar*, and *Prometheus* cases that Jazz cites in its opposition-letter brief are not applicable here.

The three cases Jazz cites in its opposition-letter brief are distinguishable. Unlike here, the accused infringers in *Convolve Inc. v. Compaq Computer Corp.*, 2006 WL 2527773 (S.D.N.Y. Aug. 13, 2006) and *Finisar Corp. v. DirectTV Group Inc.*, 424 F.Supp.2d 896 (E.D. Tex. 2006) each proposed to add more than seventy and fifty new prior-art references in their respective amended invalidity contentions. And in *Prometheus Labs, Inc. v. Roxane Labs, Inc.*, C.A. No. 11-1241 (FSH) (PS) (D.N.J.), the amended contentions sought to add entirely new defenses and prior art references. Here, on the other hand, Roxane does not seek to add any new prior-art references or entirely new defenses in its proposed amended contentions. As previously explained, the only prior art reference specifically discussed in the proposed amended contentions—CA 338—was already disclosed in the initial contentions and previously produced to Jazz. (See D.I. 177/178 at 4-5.) Moreover, under the operative Local Patent Rules or scheduling order, the accused infringers in both *Convolve* and *Finisar* were permitted to serve both Preliminary and Final Invalidity Contentions and these amendments were not permissible because of the extreme unfair prejudice to the patentees. See *Convolve* at 2006 WL 2527773, *1; see also *Finisar* at 424 F.Supp.2d at 897-98. Here, there is no provision for "Final Invalidity Contentions" in the rules or scheduling order and Jazz is not unfairly prejudiced. And in any event, Jazz has waived any right to assert unfair prejudice by failing to allege any unfair prejudice (because there is none) in its opposition-letter brief.

2. Roxane's proposed amendments are properly limited to contentions affected by the Court's adoption of a claim construction different from Roxane's proposed construction.

Each of the contentions Roxane proposes to amend has been affected by the Court's claim constructions, which differ from and thus reject Roxane's proposed constructions. Local Patent Rule 3.7(a) states that good cause exists to allow an amendment to the initial contentions where the Court's claim construction is different from the one proposed by the party seeking the amendment. There is nothing in the case law or the Local Patent Rules that prohibits amending

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contentions for claims or claim elements that are affected by the different claim construction by the Court but not explicitly containing the term construed. And Jazz cites to no such law. Even for claims or claim elements where the disputed claim terms do not appear, the context and dependency of the claims can dictate that the Court's construction affects those claims and claim elements.

For instance, Jazz misses the point when it argues that there is no good cause for Roxane's amendment of its invalidity contentions relating to claim 2 of the '431 patent (D.I. 178-2, Ex. B, Amended '431 Invalidity Contentions at 6) because the claim term "adding the gamma-hydroxybutyrate salt to the aqueous medium" that the Court construed differently from what Roxane proposed does not explicitly appear in claim 2. (D.I. 184/185 at 3.) Claim 2, however, depends from claim 1 and, therefore, necessarily includes all of the limitations of claim 1. In particular, claim 2 limits the construed term of claim 1 by specifying the "salt" (sodium) in the claim term at issue here: namely, "adding the gamma-hydroxybutyrate *salt* to the aqueous medium." Even though the disputed claim term does not literally appear in claim 2, the term is incorporated into claim 2 because claim 2 depends from claim 1. Because Roxane's proposed construction excluded "adding" by the salt forming *in situ*, Roxane did not contend in its initial contentions that any prior art references, including CA 338 (D.I. 177/178, Ex. J), teach the "adding the [sodium] gamma-hydroxybutyrate salt to the aqueous medium" element of claims 1 and 2 through *in situ* formation. The Court's rejection of Roxane's proposed construction and adoption of a construction different from Roxane's proposed construction of the term "adding" made this amendment necessary. Thus, there is good cause for Roxane's proposed amendment to its contentions relating to claim 2 of the '431 patent, just as much as there is good cause for the amendment of Roxane's contentions relating to the "adding..." element of claim 1.

Similarly, the Court can disregard Jazz's objections to Roxane's proposed amendments to the invalidity and noninfringement contentions of the '106, '107 and '059 patents on the basis that the claim elements for which Roxane proposes amendments do not contain any disputed claim terms. (See D.I. 184/185 at 2.) Because claim terms that appear in more than one claim must be construed consistently throughout the patents and across related patents, *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342 (Fed. Cir. 2001); *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1293 (Fed. Cir. 2005), any claim or claim element relating to the "controls for distribution" and their selection should be dealt with consistently across the '106, '107 and the '059 patents. Even if the disputed claim terms "selecting ... multiple controls," "places controls," "controls selected from the group consisting of," and the "controls comprising" do not literally appear in those elements to which Roxane proposes amendments, each of those elements still relate to the "controls for distribution." Because Roxane's proposed amendments are necessitated by the Court's rejection of Roxane's construction of the disputed claim terms contained in those elements, Roxane must also seek amendment for those elements relating to the "controls" that do not contain the disputed claim terms to maintain consistency across claims and related patents. (See, e.g., D.I. 178-3, Ex. C, Amended '106 Invalidity Contentions at 25, 54,

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85, 113; D.I. 178-4, Ex. D, Amended '107 Invalidity Contentions at 40, 86; D.I. 177, Ex. F, Amended Noninfringement Contentions at 11-13, 22, 23, 34-36, 45-47, 58-62, 72-76.)

3. Seeking amendment of a contention for a claim element containing a disputed claim term before the Court issues its *Markman* order is inefficient and should not be required.

Jazz is incorrect in arguing that Jazz's different proposed constructions of claim elements containing the terms "adjusting the pH" or "pH adjusting agent" in claims 1 and 6 of the '431 patent (D.I. 178-2, Ex. B, Amended '431 Invalidity Contentions at 5, 9) required Roxane to seek leave to amend its contentions pursuant to Local Patent Rule 3.7(d) before the *Markman* ruling. (D.I. 184/185 at 4.) The reason is simple: the Court might have adopted Roxane's construction of "pH adjusting agent" and [REDACTED] Common sense dictates waiting until the Court issued its construction to determine whether amendment was ever necessary. Otherwise, the parties would be left with proposing a myriad of interim provisional contentions.

In fact, the Court unexpectedly rejected both Jazz's and Roxane's proposed constructions of the term "pH adjusting agent," and formulated its own construction *sua sponte*. Roxane had no way of knowing whether the Court would adopt either party's proposed construction, or come up with its own construction, as it did. There was no way of knowing whether an earlier provisional amendment of its contentions relating to "adjusting the pH" or "pH adjusting agent," based on Jazz's proposed construction of those terms, would have been useless. It would be inefficient to require, as Jazz proposes, that Roxane seek amendment of its contentions for a claim element containing a disputed claim term in response to Jazz's infringement contentions, before the Court decides on the final construction of the claim terms. Such interim amendments could lead to the need for serial amendments of contentions: the first, provisional amendment of invalidity and noninfringement contentions after infringement contentions are served (based on Jazz's proposed construction), and a second amendment following the Court's *Markman* ruling rejecting both parties proposed constructions. Surely the Rules do not intend such a result.

4. The Local Patent Rules do not require an actual construction of claim terms by the Court.

There is no support for Jazz's argument that Local Patent Rule 3.7 requires that there be an actual claim construction by the Court. (See D.I. 184/185 at 3.) The Rule requires only that the Court's construction differ from that proposed by the party seeking amendment. Where Roxane sought a construction narrower than no construction and the Court rejected Roxane's construction in favor of no construction, that is a "different" construction. Roxane should be allowed to amend its contentions to conform to the Court's different and broader construction.

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This is especially the case with regard to the claim term “adding the gamma-hydroxybutyrate salt to the aqueous medium” in claim 1 of the ‘431 patent. The Court did state that it declined to construe this claim term. (D.I. 151 at 9-11.) The Court, however, in rejecting Roxane’s proposed construction that the GHB salt must be added *externally*, stated that it does not matter “how [the salt] gets there. ... There is no limitation how it gets there.” (D.I. 151 at 11.) Thus, the Court’s construction of that term is different from what Roxane proposed. Roxane’s proposed amendments (D.I. 178-2, Ex. B, Amended ‘431 Invalidity Contentions at 3-4, 6) relating to the “adding” claim element in independent claim 1 and dependent claim 2 were affected by the Court’s explicit rejection of Roxane’s construction such that good cause exists for the proposed amendments.

Jazz’s additional complaint about Roxane’s use of the phrase “computer decision” in its letter-brief is merely an attempt to obfuscate the issue and conjure up an argument that Roxane is overstepping its rights under Local Rule 3.7(a). (D.I. 184/185 at 3-4.) Nothing could be further from the truth. Roxane’s reference to the “computer decision” was simply an attempt to provide a shorthand reference to the control-selection step performed by the exclusive central computer system (in the context of the ‘106 patent) or computer processor (in the context of the ‘107 and ‘059 patents). That Roxane did not use the specific words “computer decision” in its contentions should have no effect on whether there is good cause for Roxane’s proposed amendments. Roxane’s initial contentions disclosed prior art that showed a computer making the “decision to include a specific control” or performing the control selection because that was how Roxane proposed that the relevant claim terms should be construed. As previously explained, because the Court’s *Markman* order rejected Roxane’s narrower proposed construction, seemingly broadening the claims to allow use of the controls without a decision to select the controls, Roxane proposes to amend its invalidity and noninfringement contentions for the ‘106, ‘107, and ‘059 patents. (See D.I. 178-3, Ex. C, Amended ‘106 Invalidity Contentions at 16-17, 24-25, 45-47, 54, 76-77, 84-85, 105-06, 113; D.I. 178-4, Ex. D, Amended ‘107 Invalidity Contentions at 16-17, 39-40, 60-61, 85-86; D.I. 178-5, Ex. E, Amended ‘059 Invalidity Contentions at 28-29, 44, 79; D.I. 177, Ex. F, Amended Noninfringement Contentions at 4-13, 15-24, 26-36, 38-47, 50-62, 64-76.)

5. The Local Patent Rules do not dictate the type of amendment Roxane could propose.

Contrary to Jazz’s argument, good cause may exist for any type of amendment affected by the Court’s *Markman* ruling rejecting Roxane’s proposed constructions. Jazz’s re-characterization of Roxane’s proposed amendments as a “re-wording” of its contentions is incorrect. Roxane’s proposed amendments are not stylistic—they are necessary because the Court rejected Roxane’s proposed constructions that the claim terms relating to the “control selection” included the phrase “and no others.” (See D.I. 178-3, Ex. C, Amended ‘106 Invalidity Contentions at 16-17, 25-26, 45-47, 54, 76-77, 84-85, 105-06, 113; D.I. 178-4, Ex. D, Amended

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‘107 Invalidity Contentions at 16-17, 39-40, 60-61, 85-86; D.I. 178-5, Ex. E, Amended ‘059 Invalidity Contentions at 28-29, 44, 79.) [REDACTED]

Jazz incorrectly accuses Roxane of merely “polishing” the prose of Roxane’s contentions on the ‘106, ‘107 and ‘059 patents. (D.I. 184/185 at 5-6.) Jazz is feigning ignorance of the fact that every change to a claim construction can have large repercussions to the claim scope and, hence, invalidity and/or noninfringement. Even though the Court’s constructions appear to cause only slight changes to Roxane’s proposed constructions, the Court’s constructions had the effect of removing limitations from Roxane’s proposed constructions thereby broadening the claims being analyzed. Of course, when claims are broadened, different arguments are required than those based on rejected narrower claim constructions. And that is what Roxane proposes to do here.

* * *

For the reasons set forth above and in its November 5, 2012 letter, Roxane respectfully requests that the Court grant Roxane’s request for leave to amend its invalidity and noninfringement contentions as set forth in Exhibits A through F of D.I. 177/178.

Should the Court have additional inquiries regarding this request or regarding Roxane’s proposed amendments, we are available to address those inquiries at the Court’s convenience. We thank Your Honor for your time and consideration of this matter.

Respectfully submitted,

/s/ Theodora McCormick
Theodora McCormick

cc: Magistrate Judge Cathy L. Waldor
All Counsel of Record (via ECF)